

## REMARKS

Claims 1-6, 21, 22, and 25 are pending in this application of which claims 1, 21, and 22 are currently amended and claim 25 is new. Claims 14-18, 23, and 24 are hereby cancelled. Entry of the claim amendments, new claim 25, reconsideration of claims 1-6, 21, and 22, and consideration of claim 25 is respectfully requested.

### New Claim 25

Claim 25 further limits claim 21 by requiring that the primer solution is further configured to enhance the performance of the tooth whitening composition applied to the tooth surface after application of the primer solution by disrupting a pellicle of the tooth. The effect of disrupting the pellicle of the tooth with the primer solution is supported by the specification, for example, on page 16 at lines 15-17.

### Claim Rejections

Claims 21-22 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 21-22 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ambuter et al. (US 5,997,764). Claims 1-6 and 14-17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Howes (US 2002/0098246). Claims 1-4, 6, 14-18, and 23-24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over van den Bosch (US 6,017,515). Claims 1-6, 14-17, and 21-24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jung (US 2006/0060819).

#### Rejections under 35 U.S.C. §112, First Paragraph

Claims 21-22 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner notes that “[a]lthough Applicant has defined synergistically, they make no other reference to a synergistic effect any where else in the specification,” but that the specification does “disclose[s] enhancing the effects of the whitening compositions” (Office action page 2). Claim 21 has been amended to remove the term “synergistically.” This amendment overcomes the Examiner’s rejection. Accordingly, the Applicant requests that the Examiner withdraw the 35 U.S.C. §112, first paragraph rejections of claim 21, and claim 22 depending therefrom.

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#### Rejections under 35 U.S.C. §112, Second Paragraph

Claim 18 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is moot in view of the cancellation of claim 18 herein.

#### Rejections under 35 U.S.C. §102(b)

Claims 21-22 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ambuter et al. As amended, independent claim 21 recites a composition comprising a primer solution and a flavoring agent in an amount of between about 0.001 and 5% by weight of the total composition. The primer solution comprises hypochlorite. Ambuter et al. does not anticipate claim 21 because Ambuter et al. does not specifically teach a composition of a flavoring agent in combination with hypochlorite, and also does not teach a flavoring agent in the specific amount of between about 0.001 and 5% by weight.

Turning first to the limitation of a flavoring agent in combination with hypochlorite, the Applicant acknowledges that Ambuter et al. does disclose both hypochlorite and flavors and does teach that flavors or sweeteners can be added to at least some of the disclosed thickened bleach compositions. However, Ambuter et al. discloses a number of different thickened bleach compositions, never specifically puts hypochlorite and flavors together in any disclosed embodiment, and for the reasons presented below, it is clear that Ambuter et al. would not put flavors in the thickened bleach compositions that comprise hypochlorite.

In the Background of the Invention section of Ambuter et al. there is a teaching that

[a]lkali metal hypohalite bleaches have long been used in household cleaning products and the textile and paper industries for the bleaching and cleaning of fabrics and wood fibers. They are also commonly used in cleaning products for disinfecting purposes. A typical alkali metal hypohalite is sodium hypochlorite. Peroxygen bleaches are less harsh than hypohalite bleaches and do not release objectionable gases or odors. This makes the use of such bleaches far more versatile, especially for personal care, *oral care*, and pharmaceutical compositions. (col. 1 lines 14-23, emphasis added).

Here, Ambuter et al. teaches that peroxygen bleaches are less harsh than hypohalite bleaches, such as sodium hypochlorite, making peroxygen bleaches suitable for oral care applications. The implication is that hypohalite bleaches, such as sodium hypochlorite, are too harsh and therefore not suitable for oral care applications.

In the Summary of the Invention section, Ambuter et al. provides that “[t]he present invention provides thickened bleach compositions having improved rheological properties and stability. The bleach compositions are useful for a variety of applications, including household,

personal care, pharmaceutical, textile, and industrial applications.” (col. 4 lines 40-44). The Applicant notes that in the Background section Ambuter et al. draws a distinction between personal care products and oral care products, yet with reference to the invention Ambuter et al. cites only personal care products and omits oral care products. Oral care products are not otherwise mentioned in Ambuter et al.

Lastly, the Applicant notes that the only reference in Ambuter et al. to flavoring agents is in a paragraph directed to “Other Optional Materials” which lists flavors and sweeteners at the end of a laundry list of other additives including “bleach activators, solvents, suds suppressers, corrosion inhibitors, fluorescent whitening agents, chelating agents, anti-redeposition agents, dispersants, dye scavengers, enzymes, emollients, humectants, preservatives, film forming and soil release polymers,” a long list of hydrotropes, “the clays and the abrasives disclosed in U.S. Pat. No. 3,985,668” “include[ing] calcium carbonate, perlite, silica sand, quartz, pumice, feldspar, tripoli, and calcium phosphate,” as well as “alkali metal salts of amphoteric metal anions,” “dyes, pigments, fragrances, [and] perfumes.” (col. 11 lines 22-45).

In view of the above, it is clear that Ambuter et al. recites flavors and sweeteners as just two of many possible additives that one might add to some of their compositions. The Applicant does not read Ambuter et al. to teach that all of the disclosed thickened bleach compositions inherently can include any and all of the listed other optional materials, but rather that any of the listed other optional materials may be used in some of the thickened bleach compositions. Clearly, Ambuter et al. did not try all possible permutations of these other materials with each of the disclosed thickened bleach compositions and certainly did not go so far as to describe or

claim any particular compositions that include flavors or sweeteners.

Accordingly, it is clear that Ambuter et al. was not particularly aimed at oral care products, Ambuter et al. does not note any particular compositions as suitable for oral care applications, and Ambuter et al. only lists sweeteners and flavors at the end of a long list of other possible additives. To the extent that Ambuter et al. does suggest adding sweeteners or flavors to any of the thickened bleach compositions, the addition would be made to the peroxygen bleaches which were noted as suitable for oral care, and not the hypochlorite bleaches, such as sodium hypochlorite, that are recognized as too harsh for oral care applications. For this reason the Applicant asserts that although “flavor” and “hypochlorite” are both words found in Ambuter et al., when the reference is considered as a whole, Ambuter et al. simply does not teach adding a flavoring agent to a hypochlorite.

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However, even if, *arguendo*, Ambuter et al. is construed to teach adding a flavoring agent to a hypochlorite, Ambuter et al. simply does not teach a flavoring agent in the specific amount of between about 0.001 and 5% by weight. For at least these reasons, Ambuter et al. does not anticipate claim 21 or claim 22 depending therefrom. The Applicant therefore requests that the Examiner withdraw the 35 U.S.C. §102(b) rejections of claims 21 and 22.

#### Rejections under 35 U.S.C. §103(a)

Claims 1-6 and 14-17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Howes. The rejections of claims 14-17 are moot in view of their cancellation herein. Claim 1, as amended, is directed to a composition produced by a method comprising applying a primer

solution to a tooth and then applying a tooth whitening composition to the tooth. The primer solution comprises hypochlorite and the tooth whitening composition comprises peroxide. As described by the present specification, “[t]he SH primer accelerates tooth whitening by disrupting the acquired pellicle and establishing a pH environment at facial surface and sub-surface of the teeth” (page 16 lines 15-17). The Applicant asserts that the composition formed at the tooth surface by the claimed method is the product of the reaction of the pellicle with the primer followed by the further reaction of that product with the tooth whitening composition. Because the pellicle is “a viscous composite biological structure which comprises saliva, glycoprotein, bacteria, minerals, and other compounds and components” (page 13 lines 20-22) and is disrupted by the primer, it follows that the resulting composition will be different if the method recited by claim 1 is followed than the composition that will result if the primer and tooth whitening composition are applied simultaneously, or if the tooth whitening composition is applied before the primer. As shown below, Howes teaches both simultaneous application of peroxide and hypochlorite, and sequential application with the peroxide preceding the hypochlorite, but does not teach or suggest sequential application with the hypochlorite preceding the peroxide, and therefore does not teach the composition that results from the method recited in claim 1.

Howes does not teach a composition that reads on the composition produced by the method of claim 1. Although Howes does contemplate treating dental plaques (paragraph [0123]) and teaches that “the source of peroxide and source of hypochlorite anion may be administered sequentially” (paragraph [0032]), much of the discussion pertains instead to their simultaneous delivery (e.g., paragraph [0032]). To the extent that Howes teaches sequential

delivery, the Applicant notes that Howes teaches the sequence being the source of peroxide and source of hypochlorite anion (paragraph [0032]; see also claim 6), and “[t]he spray trigger is actuated, resulting in a sequential spray of the hydrogen peroxide solution followed by the hypochlorite solution” (paragraph [0167]), and in no instance teaches or suggests that the hypochlorite should be administered first followed by the peroxide as in the method recited by claim 1. Howes certainly does not teach or suggest specifically applying the hypochlorite to a tooth and then applying the peroxide to the tooth.

Furthermore, per MPEP §2145:

Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467. See also, e.g., *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901.

Here, the claimed invention yields unexpectedly improved properties. The Background section of the present application provides in Table 1 a summary of over-the-counter peroxide tooth whitening methods and in Table 1 the best results are 2.3 hours of treatment per shade of improvement. By contrast, Table 3 shows results obtained for the present invention, and as noted in the discussion following Table 3, 25% of patients obtained tooth whitening of 6 shades or greater in only 10 minutes.

Since Howes does not teach or suggest the claimed composition, and since the Applicant has shown evidence of secondary considerations in the form of unexpectedly improved

properties, the Applicant requests that the Examiner withdraw the 35 U.S.C. §103(a) rejections of claims 1-6 over Howes.

Claims 1-4, 6, 14-18, and 23-24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over van den Bosch. The rejections of claims 14-18 and 23-24 are moot in view of their cancellation herein. As noted above, claim 1 is directed to a composition produced by a method comprising applying a primer solution to a tooth and then applying a tooth whitening composition to the tooth. The primer solution comprises hypochlorite and the tooth whitening composition comprises peroxide. As also provided above, the composition on the surface of the tooth will be different if the presently claimed method is followed rather than if the primer and tooth whitening composition are applied simultaneously, or if the tooth whitening composition is applied before the primer.

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Van den Bosch teaches methods for treating both vital and avital teeth. In the methods directed to vital teeth, a preparation is applied either to the outside of a tooth which is then capped, or to the inside of the cap that is fitted over the tooth. (col. 5 lines 17-40). “[T]he preparation for bleaching teeth ... is preferably prepared by combining constituents (a) and (b)” (col. 2 lines 32-34) where “(a) [is] a gel or paste in which a component (i) is present” (col. 1 line 63), “(b) [is] a gel or paste in which a component (ii) is present” (col. 2 line 1), and “a hypohalite is used as component (i) and a borate as component (ii).” (col. 2 lines 40-41). In either method, therefore, the hypohalite and borate components are combined before being applied to the surface of the tooth. As noted above, the composition on the surface of the tooth will be different if the presently claimed method is followed than if the primer and tooth whitening



composition are applied simultaneously. Thus, the methods for treating vital teeth taught by van den Bosch do not result in the claimed composition of claim 1.

In the method directed to avital teeth, on the other hand, van den Bosch teaches the steps of “treatment of a cavity in a tooth with an etchant,” “treatment of the cavity with a cleaning agent,” and “application of at least one layer of a constituent which comprises component (i). and at least one layer of a constituent which comprises component (ii), individually and layer by layer” (col. 7 lines 1-8). In this method the pellicle (to the extent that any even exists in the cavity) is first removed by the steps of etching and cleaning prior to the application of the layers comprising components (i) and (ii). Since the pellicle is first removed, the hypohalite does not react with the pellicle and therefore the borate does not react with the product of a reaction between the pellicle and the hypohalite. Thus, the composition produced in the tooth cavity by this method does not result in the claimed composition of claim 1.

Further, although van den Bosch is directed to preparations for bleaching teeth, van den Bosch notes that for bleaching vital teeth “[t]he sleeve or cap then remains in place for at least 6 hours, preferably 9 hours” (col. 5 lines 10-11) and van den Bosch does not indicate how much improvement was obtained in that time. With respect to avital teeth, van den Bosch notes that “the bleaching action is complete in 3-6 weeks.” (col. 7 lines 12-14). Clearly, whatever improvement was obtained for vital teeth by van den Bosch took substantially longer to achieve with the simultaneous application of hypochlorite and peroxide compared with the 6 shades or better improvement in 10 minutes reported for the present invention. Likewise, whatever improvement was obtained for avital teeth by van den Bosch took substantially longer to achieve

with the layered application of peroxide and hypochlorite compared with the results reported for the present invention.

Since none of the methods of van den Bosch teach or suggest the claimed composition, and since the Applicant has shown evidence of secondary considerations in the form of unexpectedly improved properties, the Applicant requests that the Examiner withdraw the 35 U.S.C. §103(a) rejections of claims 1-4 and 6 over van den Bosch.

Claims 1-6, 14-17, and 21-24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Jung. The rejections of claims 14-17, 23, and 24 are moot in view of their cancellation herein. As noted above, claim 1 is directed to a composition produced by a method comprising applying a primer solution to a tooth and then applying a tooth whitening composition to the tooth. The primer solution comprises hypochlorite and the tooth whitening composition comprises peroxide. As also provided above, the composition on the surface of the tooth will be different if the presently claimed method is followed than if the primer and tooth whitening composition are applied simultaneously.

Jung teaches that “the dentifrice composition of the present invention consists of a first paste containing hydrogen peroxide and a second paste containing sodium hypochlorite, wherein the first paste and the second pastes are filled into a dual container with a partition or separate containers.” (Abstract). Clearly, in Jung the pastes containing hydrogen peroxide and sodium hypochlorite are applied to the teeth simultaneously. For the reasons provided above, the composition on the surface of the tooth treated by the dentifrice of Jung will be different than if

the presently claimed method were followed. Thus, Jung does not result in the claimed composition of claim 1.

Independent claim 21 is directed to a composition comprising a primer solution comprising hypochlorite and having a pH greater than about 8.5 to about 13. Claim 1 also requires the same pH range for the primer solution. Jung does not discuss the pH of the disclosed dentifrices. The Examiner has previously argued that it would be obvious to optimize the pH within the claimed range. The Applicant disagrees. Specifically, although MPEP §2144.05 provides that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation,” (citing *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)), this only applies where the general conditions of a claim are actually disclosed in the prior art.

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To better appreciate what is meant by the “general conditions of a claim” requirement, consider the case of *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) in which the primary reference showed the basic structure of the claimed water treatment device but was “silent regarding quantitative design parameters” (Chisum on Patents, §5.04[1][f][iv]). Here, the claimed tank was the same as in the prior art; all the inventors had done was recognized a particular ratio of tank volume to contactor ratio. In *In re Antonie* the general conditions of the water treatment device claim were clearly disclosed in the water treatment device of the prior art because the inventors were merely optimizing the prior art water treatment device.

The Applicant believes that it is worthwhile to call attention to the distinction between

the legal concept of anticipation under 35 U.S.C. §102 and the “general conditions of a claim.”

A reference anticipates a claim if it teaches all of the claim’s limitations, whether or not the reference bears any resemblance to the claimed invention. A claim to a submarine comprising an engine, a pressurized and elongated passenger compartment, and a radar system would read on a commercial airliner, but the commercial airliner would not satisfy the general conditions of the submarine claim. Thus, it is not sufficient to simply argue that because the Examiner takes the position that Jung anticipates every limitation of claim 21 other than the particular pH range, therefore Jung satisfies the general conditions of claim 21 and it would be obvious to optimize the teaching of Jung within particular range of a pH greater than about 8.5 to about 13. By this reasoning it would be obvious to optimize the commercial airliner to operate at a depth of between 50 and 500 meters because it otherwise anticipates the submarine claim. During examination, there needs to be some consideration regarding whether the prior art satisfies the general conditions of the claim, separate from the consideration regarding whether the claim is otherwise anticipated, else the limitation on the rule set forth by *In re Aller*, that the general conditions of a claim are disclosed in the prior art, has no meaning.

In *In re Antonie*, the general conditions of the water treatment device claim were disclosed in the water treatment device of the prior art, thus it was permissible to consider whether it would have been obvious to optimize within the claimed range<sup>a</sup>. Here, Jung teaches a two-part dentifrice paste. The Applicant clearly has not set out to optimize the dentifrice of Jung. In the present application, by contrast, a primer solution is at issue. The Examiner has not shown that the dentifrice paste of Jung discloses the general conditions of the claimed primer

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<sup>a</sup> It was not obvious because the claimed ratio was not an art recognized results effective variable. (See MPEP §2144.05)

solution, and the Applicant argues that the dentifrice paste clearly does not disclose the general conditions of the claimed primer solution. The primer solution is meant to “penetrate[] and disrupt[] the acquired pellicle, [] penetrate[] the surface of the enamel and into the sub-surface of the enamel of the tooth and begin[] to oxidize stains” **before** the peroxide tooth whitening gel is applied (page 9 lines 1-5). In Jung, the hypochlorite and peroxide of the dentifrice are applied together to “prevent[] dental caries and periodontal diseases” (paragraph [0022]) and “eliminate plaque” (Abstract) in addition to whitening. Further evidencing that the dentifrice of Jung does not disclose the general conditions of the claimed primer solution, the dentifrice taught by Jung includes “general components such as abrading agents, wetting agents, foaming agents, bonding agents ... and other components that are in ointment phase.” (paragraph [0049]).

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The Applicant contends that the pH requirements for a dentifrice will be different than those for the claimed primer and not necessarily in the range of greater than about 8.5 to about 13. Further, the mere presence of hypochlorite as a component of the dentifrice does not dictate what an appropriate pH will be. Put another way, if a group of product designers were trying to optimize the pH of a dentifrice, the fact that hypochlorite was a component would not drive the designers to particularly optimize the pH within the range of greater than about 8.5 to about 13. The Applicant believes that considerations such as avoiding chemical burns in the mouth would be one factor that would tend to weigh against optimizing the pH of a dentifrice in the range of greater than about 8.5 to about 13.

Moreover, even if, *arguendo*, Jung does disclose the general conditions of the claimed primer solution, the courts have recognized “exceptions to this rule in cases where the results of

optimizing a variable, which was known to be result effective, were unexpectedly good” *In re Waymouth*, 499 F.2d 1273, 182 USPQ 290 (CCPA 1974). The Applicant contends that the unexpectedly improved properties described above are unexpectedly good and therefore this exception should apply.

The Applicant also wishes to address the statement made by the Examiner that “[i]t may be concluded [that] a solution comprising hypochlorite as the only constituent would have a pH of hypochlorite.” (Office action page 5). While the quoted statement was not made with reference to Jung, the Applicant believes the comment to be relevant here as it evidences an incorrect view of the claims and what will read on the claims. Claim 1, to which the comment was originally directed, uses the transitional phrase “comprising” and therefore is not directed to a solution in which hypochlorite is the only constituent. Likewise, claim 21 uses the transitional phrase “comprising” and therefore is also not directed to a solution having hypochlorite as the only constituent (besides the fact that a flavoring agent is also a limitation of the claim). Thus, the Examiner appears to be viewing the scope of the claims incorrectly.

Further, the Examiner appears to be arguing that hypochlorite inherently has a pH, that pH is in the range required by claim 1 (and claim 21), and that any composition that includes hypochlorite will necessarily have a pH in that range. As is well understood, pH is a measure of the acidity/basicity of a solution which is a function of the concentrations of the various dissolved constituents. A glass of neutral water to which a very small quantity of hypochlorite is added will have a pH only barely greater than 7.0, for example. One cannot readily conclude what the pH of the dentifrices taught by Jung would be, and the Applicant asserts that the pH

will necessarily be a function of the concentration of hypochlorite as well as the concentrations of the other soluble constituents including the peroxide and any foaming agents, abrasives, wetting agents, and bonding agents. Therefore, it is clear that the pH will not necessarily be in the claimed range just because hypochlorite is a further constituent.

Lastly, the improvement in teeth whitening reported by Jung was obtained over the time scale of months. As can be seen from Tables 9-15, results were reported after 1, 2, and 3 months of using the dentifrice. The best result was seen for embodiment 1 (Table 9) which went from an initial color reading of 62.3 to a color reading of 69.0 after three months. For comparison, the best improvement from the comparative examples in Jung was seen with comparative example 2 (Table 5) for which the color reading improved from 62.50 to 64.2 after three months. In short, the improvement by Jung took substantially longer to achieve with the simultaneous application of hypochlorite and peroxide in a dentifrice compared with the 6 shades or better improvement in 10 minutes reported for the present invention.

In sum, just because Jung employs hypochlorite as a constituent in dentifrices does not mean that the pH of the dentifrices will be in the range of greater than about 8.5 to about 13. Further, since the dentifrices of Jung do not disclose the general conditions of the claimed primer, it would not be obvious to optimize the pH of the dentifrices to be greater than about 8.5 to about 13, but even if Jung did disclose the general conditions of the claimed primer, claim 21 is not obvious because of unexpectedly good results. The simultaneous application of hypochlorite and peroxide would not result in the claimed composition of claim 1. Finally, the Applicant has shown evidence of secondary considerations in the form of unexpectedly

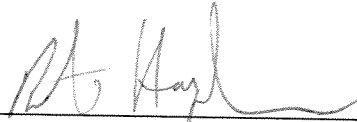
improved properties. For at least these reasons, the Applicant requests that the Examiner withdraw the 35 U.S.C. §103(a) rejections of claims 1-6, 21, and 22 over Jung.

### CONCLUSION

All claims are now allowable and therefore the Applicant requests a Notice of Allowance. Should the Examiner have further questions, the Applicant's attorney can be reached at the number provided below.

Respectfully submitted,

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Robert D. Hayden Reg. No. 42,645  
PETERS VERNY, LLP  
425 Sherman Avenue, #230  
Palo Alto CA 94306

Tel: (650) 324-1677

Fax: (650) 324-1678